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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/563,785	04/25/2006	John Nolting	PA1394	2982

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EXAMINER	
HELM, CARALYNNE E	
ART UNIT	**PAPER NUMBER**
1615	

NOTIFICATION DATE	DELIVERY MODE
11/17/2008	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

rs.vasciplegal@medtronic.com

Office Action Summary	Application No.	Applicant(s)	
	10/563,785	NOLTING, JOHN	
	Examiner	Art Unit	
	CARALYNNE HELM	1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-29* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-29* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *1/06*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 7-11, 19-22, and 26-27 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 7 recites the limitation "each timing coating…" in line 1. There is insufficient antecedent basis for this limitation in the claim since its parent claim does not recite the presence of timing coatings

For the sake of application of prior art, this claim is interpreted as a device with all the limitations of claim 1 as well as timing coatings that prevent the release of the therapeutic agent , as recited.

Claims 8-11, 19-22, and 26-27 recite a “mid-portion” or “middle” of the stent. This description does not clarify if this is a radial location or a longitudinal location along the length of the stent. For the sake of application of prior art, this descriptor was interpreted to refer the middle or mid-portion along the length of the stent.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-2, 4, 8, 12-14, and 19 are rejected under 35 U.S.C. 102(b) as being anticipated by Sirhan et al. (US Patent No. 6,471,980).

Sirhan et al. teach a set of intravascular devices that deliver therapeutic agents that minimize or inhibit restenosis (see abstract). Sirhan et al. teach a stent with a plurality of coating layers that cover its length and where each contains a therapeutic agent (see Figure 7, column 8 line 24, column 11 lines 41-43; instant claims 1 and 12). The configuration shown indicates that the distal, proximal and middle regions of the stent have these therapeutic coatings (see instant claims 8 and 19). These coating layers are taught to include biodegradable/bioerodible polymers (see column 11 lines 1-4; instant claims 4 and 13). It is also taught that these devices are delivered by balloon dilation catheter (requiring that the stent and catheter be operably coupled) (see column 14 lines 11-13; instant claim 1). Claims 1 and 12 recite the intended use, “the therapeutic agents being released sequentially to inhibit restenosis adjacent to the ends of the stent.” A recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is

capable of performing the intended use, then it meets the claim. Since the taught devices provide a layered drug configuration, it would be capable of sequential delivery of these therapeutics to inhibit restenosis. Further, Sirhan et al. teach a particular embodiment where different drugs are present in separate layers and envisioned to be released sequentially (see example 17). In addition these drugs include proteins and inhibitors of de novo nucleotide synthesis (anti-proliferative agents) (see instant claims 2 and 14). Thus claims 1-2, 4, 8, 12-14, and 19 are unpatentable over Sirhan et al.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

The four factual inquiries of Graham v. John Deere Co. have been fully considered and analyzed in the rejections that follow.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-4, 10-15, and 21-22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sirhan et al. (US PGPub No 2003/0033007 – see IDS - referred to henceforth as Sirhan et al reference B) in view of Sirhan et al.

Sirhan et al. reference B teaches that an edge effect phenomenon is known to occur in patients that have had coronary stents deployed within them (see paragraph 19). Beyond the edges of the implanted stent severe stenosis often develops, thus the inventors developed a device that focuses drug delivery from the proximal and distal ends of a stent device that extends beyond the ends of the stent (see paragraph 22). The intermediate portion (mid-portion) of the stent between the distal and proximal regions is taught to have a therapeutic agent that is different and released with a different kinetic profile than that released from the ends (see paragraph 51; instant claims 10). These therapeutic agents are taught to be present in coating form on the stent (see paragraph 59). Particular therapeutic agents envisioned on the device,

separately or in combination, include dexamethasone, rapamycin, rapamycin analogs, and prednisone (see paragraph 35; instant claims 3 and 15). Sirhan et al. reference B teaches that the stent is deployed via a balloon catheter (requiring that the stent and catheter be operably coupled) (see paragraph 48; instant claim 1). In addition, the presence of a biodegradable (bioerodible) rate controlling element (layer) that impedes the delivery of drug form the intermediate region (midportion0 as compared to the ends to different degrees is also taught (see paragraphs 25 and 33). Sirhan et al. reference B also teaches that the therapeutic has a higher diffusion rate from the device at the ends than in the intermediate region (mid-portion) (see claim 7; instant claims 11 and 22). Sirhan et al. reference B does not teach a multi-layered configuration of drug containing coatings.

Sirhan et al. teach a set of intravascular devices that deliver therapeutic agents that minimize or inhibit restenosis (see abstract). Sirhan et al. teach a stent with a plurality of biodegradable/bioerodible coating layers that each contains a therapeutic agent (see Figure 7, column 8 line 24, column 11 lines 41-43, column 11 lines 1-4; instant claims 1, 4, and 12-13). Since this layered configuration was known at the time of the invention to address the same pathology as that of Sirhan et al. reference B, it would have been obvious to one of ordinary skill in the art at the time of the invention to use this multi-layer configuration of drug containing layers to allow for the sequential delivery of a collection of therapeutic agents from the distal and proximal ends of the stent (see example 17; instant claims 1-2, 12, and 14). Therefore claims 1-4, 10-15, and 21-22 are obvious over Sirhan et al. reference B in view of Sirhan et al.

Claims 12-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Miller et al. (US PGPub No. 2003/0153983).

Miller et al, teach medical devices with a set of layers on their surface that can each contain a different bioactive (see abstract and paragraph 55; instant claim 12). In particular, Miller et al. envision coronary stents as medical devices within their invention (see paragraph 92; instant claim 12). One of ordinary skill in the art at the time of the invention would have found it obvious to select a particular set of therapeutic agents pertinent to the body region treated by the device (e.g. coronary artery). Therapeutic agents considered by Miller et al. are taught to include paclitaxel, dexamethasone, and non-steroidal anti-inflammatory agents (see paragraphs 45 and 49; instant claims 14-15). These therapeutic containing layers are also taught to be composed of biodegradable (bioerodible) polymers (see paragraphs 40-41; instant claim 13). Miller et al. also teach that the layers are applied to any portion of the device, thus it also would have been obvious to apply them to the full length of the device (which includes the distal, proximal, and mid-portions) (see paragraph 50; instant claims 12 and 19-20). The layered configuration contains a plurality of barrier layers (timing coatings) and a plurality of therapeutic agent containing layers that alternate on the surface of the device (see paragraph 62; instant claim 16). These layers are taught to impede the release of therapeutic agents from the device (see paragraph 56; instant claim 18). Embodiments are envisioned where a barrier layer (timing coating) covers each of three therapeutic agent containing layers (see paragraph 62; instant claims 12 and 20). The

barrier layers (timing coatings) are also taught to be composed of biodegradable polymer (see paragraph 58; instant claim 17). In view of these teachings, it would have been obvious to one of ordinary skill in the art at the time of the invention to employ bioerodible polymers in the barrier layers and/or the therapeutic containing layers. Therefore claims 12-20 are obvious over Miller et al.

Claims 1-3 and 5-9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Miller et al. as applied to claims 12 and 14-20 above, and further in view of Sirhan et al. reference B.

Miller et al. make obvious a coronary stent with alternating barrier layers (timing coating) and therapeutic containing layers arranged such that the distal and proximal ends have a plurality of each while the mid-portion has at least one of each. In addition, the claimed therapeutic agents, release kinetics and bioerodability are also obvious over Miller et al (see instant claims 1-3 and 5-9). Miller et al. do not teach that the coronary stent is operably coupled to a catheter.

Sirhan et al. reference B teach that coronary stents are deployed via a balloon catheter (requiring that the stent and catheter be operably coupled) (see paragraph 48; instant claim 1). Therefore it would have been obvious to one of ordinary skill to operably combine a catheter and the taught coronary stent. Therefore claims 1-3 and 5-9 are obvious over Miller et al. in view of Sirhan et al. reference B.

Claims 23-29 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sirhan et al. reference B in view of Miller et al. as applied to claims 12 and 14-20.

Sirhan et al. reference B teaches that an edge effect phenomenon is known to occur in patients that have had coronary stents deployed within them (see paragraph 19). Beyond the edges of the implanted stent severe stenosis often develops, thus the inventors developed a device that focuses drug delivery from the proximal and distal ends of a stent device (see paragraph 22). The intermediate region (mid-portion) of the stent between the distal and proximal regions is taught to have a therapeutic agent that is different and released with a different kinetic profile than that released from the ends (see paragraph 51; instant claims 10). These therapeutic agents are taught to be present in a coating on the stent (see paragraph 59). Particular therapeutic agents envisioned on the device, separately or in combination, include dexamethasone, rapamycin, rapamycin analogs, and prednisone (see paragraph 35; instant claims 24-25). In addition, the presence of a biodegradable (bioerodible) rate controlling element (layer) in the intermediate region (mid-portion) and ends of the stent is also taught (see paragraphs 25 and 33). In addition, the stent is taught to be deployed via a balloon catheter (requiring that the stent and catheter be operably coupled) (see paragraph 48; instant claim 23). Sirhan et al. reference B does not teach a multi-layered configuration of drug containing coatings on the distal and proximal ends.

Miller et al. teach a coating configuration where different therapeutic agent containing coatings alternate with barrier layers (timing coatings) on the surface of a coronary stent. Since this particular configuration was known for its suitability in

delivering multiple drugs from a stent surface, it would have been obvious to employ it on the distal and proximal ends of the stent taught by Sirhan et al. reference B in order to confer its additional drug release beyond the ends of the stent upon implantation. This results in a stent with a tiered set of alternating barrier and therapeutic layers on the distal and proximal ends, while the intermediate region (mid-portion) contains a single pair of layers, one with therapeutic and the other a barrier layer.

The barrier layers taught by Miller et al. are actuated upon contact with physiological fluid. Once implanted, the outermost therapeutic agent would be released since it first encounters the physiological environment. Subsequently, the underlying barrier layer would contact physiological fluid and act as a diffusion barrier to the second therapeutic lying beneath it. After some time, depending upon the material chosen for these various layers, the second therapeutic would be released. As discussed above, Sirhan et al. reference B teaches that the intermediate region of the stent is coated with both a therapeutic distinct from those on the ends and a barrier layer. Like the barrier layers taught by Miller et al., it is actuated upon contact with physiological fluid which triggers the subsequent release of the therapeutic located beneath it. Therefore claims 23-29 are obvious over Sirhan et al. reference B in view of Miller et al.

Conclusion

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to CARALYNNE HELM whose telephone number is (571)270-3506. The examiner can normally be reached on Monday through Thursday 8-5 (EDT).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward or Tracy Vivlemore can be reached on 571-272-8373 or 571-272-2914, respectively. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Caralynne Helm/
Examiner, Art Unit 1615

/Tracy Vivlemore/
Primary Examiner, Art Unit 1635